

VERSION WITH MARKINGS

[27. A method for the determination of the presence of an analyte in a sample, the method comprising the steps of:

providing an element comprising a sample application zone; a detection zone located downstream from the sample application zone; a zone containing immobilized analyte or analyte analogue located between the sample application zone and the detection zone; a material that enables liquid transport between the zones; an impregnated conjugate, located upstream of the zone containing immobilized analyte or analyte analogue, that can be detached by liquid and comprises a first bioaffine binding partner capable of a specific binding reaction with the analyte to be determined and a first detectable label, wherein the first detectable label is a low molecular organic molecule; and a universal conjugate, located upstream of the zone containing immobilized analyte or analyte analogue, which can be detached by liquid and comprises a second bioaffine binding partner capable of a specific binding reaction with the first detectable label and a second detectable label,

contacting the sample application zone of the element with the sample,

contacting the sample with the impregnated and universal conjugates to react the analyte present in the sample with the impregnated and universal conjugates to form a detection complex, and

determining the presence of the detection complex in the detection zone of the element.]

[28. A method as claimed in claim 27, wherein the determining step includes optically observing the detection complex.]

[29. A method as claimed in claim 28, wherein the detection complex is detected by visual coloration.]

[30. A method as claimed in claim 27, further comprising the step of adding an elution agent to the element to transport the sample toward the detection zone.]

[31. An element for the determination of an analyte in a sample, the element comprising:

a sample application zone,

a detection zone located downstream from the sample application zone,

a zone containing immobilized analyte or analyte analogue located between the sample application zone and the detection zone,

an impregnated conjugate located upstream of the zone containing immobilized analyte or analyte analogue, which can be detached by liquid and comprises a first bioaffine binding partner capable of a specific binding reaction with the analyte to be determined and a first detectable label, wherein the first detectable label is an organic molecule, and

a universal conjugate located upstream of the zone containing immobilized analyte or analyte analogue, which can be detached by liquid and comprises a second bioaffine binding partner capable of a specific binding reaction with the first detectable label and a second detectable label.]

[32. An element as claimed in claim 31, wherein the first detectable label is digoxigenin or digoxin.]

[33. An element as claimed in claim 32, wherein the second bioaffine binding partner is an antibody to digoxigenin or digoxin.]

[33. An element as claimed in claim 32, further comprising an elution agent application zone located upstream of the sample application zone.]

[34. An element as claimed in claim 33, wherein the impregnated conjugate and the universal conjugate are located between the elution agent application zone and the sample application zone.]

[35. An element as claimed in claim 31, wherein the second bioaffine binding partner is an antibody to digoxigenin or digoxin.]

[36. An element as claimed in claim 35, wherein the second detectable label is metal particles or latex particles.]

[37. An element as claimed in claim 36, wherein the second detectable label is gold particles.]

[38. An element as claimed in claim 31, wherein the impregnated conjugate and the universal conjugate are located in the sample application zone.]

[39. An element as claimed in claim 31, further comprising an elution agent application zone located upstream of the sample application zone.]

[40. An element as claimed in claim 39, wherein the impregnated conjugate and the universal conjugate are located between the elution agent application zone and the sample application zone.]

[41. An element as claimed in claim 39, wherein the impregnated conjugate and the universal conjugate are located in the sample application zone.]

[42. A kit for determining an analyte, the kit comprising

an element comprising a sample application zone, a detection zone located downstream from the sample application zone, a zone containing immobilized analyte or analyte analogue located between the sample application zone and the detection zone, an impregnated conjugate located upstream of the zone containing immobilized analyte or analyte analogue, which can be detached by liquid and comprises a first bioaffine binding partner capable of a specific binding reaction with the analyte to be determined and a first detectable label, wherein the first detectable label is an organic molecule, and a universal conjugate located upstream of the zone containing immobilized analyte or analyte analogue, which can be detached by liquid and comprises a second bioaffine binding partner capable of a specific binding reaction with the first detectable label and a second detectable label; and
an elution agent.]